

Remarks

Claims 1-3, 5-8 and 10-24 are pending. Claims 4 and 9 are canceled. Claims 1, 2 and 5 are amended. Support for the amendments to the claims can be found, for example, in the application as filed in Example 2, pages 13-14, and the claims as originally filed. No new matter is added.

Claim rejections under 35 U.S.C. § 112

Claims 1-24 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action asserted that the application as filed did not provide support for a device comprising at least 16.5 micrograms of a second latex-labeled specific binding reagent. Claim 1 as amended states “a second latex-labeled specific binding reagent from a control latex suspension having a latex concentration of at least 1.5% w/v”. Applicants believe that the claims comply with the written description requirement. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 2 and 5 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite.

The Office Action states that claim 2 recites an analyte which is not part of the device of claim 1. Claim 1 states “...which indicates the presence and/or amount of analyte of interest in the sample...” Claim 2 has been amended to state “The device of claim 1, wherein the analyte of interest is hCG.” Therefore Applicants believe that claim 2 complies with 35 U.S.C. § 112, second paragraph.

The Office Action states that claim 5 recites an intended use of the device of claim 1 and is not further limiting. Claim 5 as amended states “The device of claim 1, wherein the second signal has a signal development time of about 1 minute.” Applicants believe that claim 5 complies with 35 U.S.C. § 112, second paragraph.

Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' representative would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

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Customer No: 63767

Respectfully submitted,
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